S.F.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

JAN 4 1996

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: Aldicarb (List A, Case 0140, Chemical 098301). Storage Stability for Soybean Processed Commodities (GLN 171-4(e, l)). Rhone-Poulenc Ag Company. CBRS No. 16514. DP Barcode D221123. MRID 43844701.

From: Stephen Funk, Chemist
Reregistration Section II
Chemistry Branch II - Reregistration Support
Health Effects Division (7509C)

Through: Andrew Rathman, Section Head
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division (7509C)

To: Jackie McQueen, CRM 63/Phillip Poli
Special Review Branch
Special Review and Reregistration Division (7508W)

The *Registration Standard Update, Residue Chemistry Chapter* (R. Schmitt, 08/20/90) noted that storage stability data were required for soybean processed commodities to support a soybean processing study (GLN 171-4(l)). The soybean processing study (MRID 40884601) showed that the combined residue of aldicarb, aldicarb sulfoxide, and aldicarb sulfone concentrated in soybean meal (1.7X) and did not concentrate in other processed commodities. However, samples were stored frozen for 5 - 8 weeks before extraction and analysis, and no data were provided on the stability of the residue of concern in soybeans and the processed commodities. The registrant (RPAC) subsequently submitted a storage stability study that was found unacceptable because complete raw data were not included. The preliminary conclusion was that aldicarb, aldicarb sulfone, and aldicarb sufoxide were stable for up to six weeks of frozen storage in/on soybeans and in soybean meal, hulls, crude and refined oil, and grain dust (R. Perfetti, CBRS 10775, DP D183798, MRID 42467302, 04/06/93). RPAC now submits additional data in a volume entitled *Aldicarb - Stability of Residues in Frozen Soybean Processed Fractions, Addendum: Quantitative Data Tables & Example*

Chromatograms, Project No. EC-92-200, 11/02/95.

Conclusions and Recommendation

The soybean processed commodities storage stability study is upgraded to fully acceptable. Adequate supporting raw data and sample chromatograms were provided. It is concluded that asulam, asulam sulfoxide, and asulam sulfone are stable (<10% loss) in/on soybeans and in crude oil, refined oil, hulls, and meal stored frozen for six weeks. These data adequately support the soybean processing study.

No additional data are required for either the soybean processing study or the soybean processed commodities storage stability study.

CBRS concludes that no food/feed additive tolerances are needed for soybean processed commodities, as defined in Table 2 (09/95), and rescinds the previous recommendation for a 0.04 ppm feed additive tolerance for the combined residues of aldicarb, aldicarb sulfoxide, and aldicarb sulfone in soybean meal.

Detailed Consideration

Tables summarizing sample weights, dilution factors, target analyte areas, and calculated concentrations for standards and samples for each commodity at each storage interval (0 day, 14 days, 28 days, and 42 days) are presented. From these data, the concentrations can be calculated using the following equation:

$$\text{ppm } (\mu g/g) = [A \times DF \times V] / W$$

where A = value from calibration (μg/ml) based on straight-line fit of 5 data points for standards, DF = dilution factor, V = final volume from extraction (ml), and W = sample weight (g). The reported recoveries have been verified by the reviewer by calculation of the analyte concentration (recovery) for selected data sets. The calculated recoveries agree with those previously summarized in Table 16, R. Perfetti, CBRS 10775, DP D183798, 04/06/93. As noted previously, results were corrected for concurrent method recoveries, and these were typically >80%. Exceptions were aldicarb in meal and hulls (>60%) and aldicarb in crude oil, soybeans, and grain dust (>70%).

A copy of the analytical method (RPAC SOP 90025) was included. A complete set of chromatograms were supplied for all 6 week storage samples. The chromatograms show baseline separations of the target analytes and no interferences. The areas agree with those tabulated in the tables.

These data confirm the previous conclusion that aldicarb, aldicarb sulfone, and aldicarb sulfoxide are stable (<10% loss each) in/on soybeans, meal, crude oil, refined oil, and hulls stored frozen for 6 weeks. The study adequately supports the soybean processing study.

It was tentatively concluded that the residue of concern does not concentrate in oil (<0.33X) but does concentrate (1.7X) in soybean meal and does concentrate slightly (1.3X) in hulls (*Registration Standard Update, Residue Chemistry Chapter*, 08/20/90). The *Update* suggested that a feed additive tolerance of 0.04 ppm, or 2 X 0.02 ppm soybean tolerance, would be appropriate, and the registrant proposed that tolerance (PP#2H5641, J. Smith, 07/24/92). CBRS recommended for the FAT, pending resolution of certain residue chemistry deficiencies. New procedures are now used to determine the need for a Section 409 tolerance or a Section 701 MRL. The expected total residue of concern in soybean meal is calculated to be the highest average field trial residue, 0.10 ppm, multiplied by the average processing factor, 1.7X, or 0.17 ppm. The expected residue is less than the RAC tolerance (0.02 ppm), and this tolerance will suffice for meal. A similar consideration applies to hulls (1.3X).

cc: S.Funk, Aldicarb Registration Standard File, SF, RF, circ.

RDI:R. Perfetti:01/04/96:Zager:01/04/96:
7509C:CBRS:S.Funk:305-5430:CM#2:RM803-A:SF(0196.1):01/02/96:01/04/96.